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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,959	12/11/2001	Johannes Aebi	20806	6321

151 7590 05/30/2003
HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
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EXAMINER

SMALL, ANDREA D SOUZA

ART UNIT PAPER NUMBER

1626

DATE MAILED: 05/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,959	AEBI ET AL.	
	Examiner	Art Unit	
	Andrea D Small	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 39,54-61 and 63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1-38,40-53 and 62 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4,5</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

I. Applicants Response:

(a) Applicants response filed 4/28/2003 has been received and entered as paper no. 8.

II. Restriction/Election:

(a) Applicant's election with traverse of group I, claims 1-60 and 62 and the election of species 5-{5-[ethyl-(2-hydroxy-ethyl)-amino]-pent-1-ynyl}-6-fluoro-2,13-dihydro indole-1-carboxylic acid 4-chloro phenyl ester in Paper No. 8 is acknowledged.

(b) Generic Concept:

Grouping of Invention I: The compounds of claim 1, X is as claimed; n is as claimed; v is as claimed; L is as claimed; A1-A4 are as claimed; W is as claimed, A5 is as claimed and wherein m is 1, i.e., compounds of claim 1 containing an indole moiety. Thus, the claims readable on this group are 1-38 in part, 40-53 in part and claim 62 in part. The remaining subject matter of claim and claims 39 and 54-61 and 63 are withdrawn from consideration as being drawn to non-elected inventions. 37 CFR 1.142(b).

(c) Traversal and Response:

The traversal of the restriction within claim 1 is on the ground(s) that restriction within a claim cannot be sustained under 35 U.S. C 121, citing *In re Weber*, 198 USPQ 328 (CCPA 1978). This is not found persuasive because:

In re Weber does not stand for restrictions within claims under 35 USC 121, rather the case holding deals with *rejection* of a claim as being an improper Markush claim under 35 USC 121. Instantly, a restriction requirement is placed on the instant claims, they are NOT being rejected as being an improper Markush claim. The entire contents of the claims will be

examined, as the remaining subject matter not being examined will be withdrawn as being drawn to non-elected subject matter, which upon the filing of a divisional application will be examined. Therefore, the case is not on point with the issues present in this case.

In the instant case, the examiner has based the restriction on statutory provisions of 35 USC 121, where the office has the authority to restrict the application to a single independent and distinct invention, where two or more inventions are claimed in one application. The guide to establishing the restriction MPEP 803 states that this may be established by a two-prong test. First, establishing that the group is independent or distinct from the other groups and second, there must be a serious burden on the examiner if restriction is required.

Claim 1 has already been established as being generic where a number of distinct species are claimed thereto. See office action of paper no. 7. Each species differs one from the other in structure and element and have each acquired separate status in the art. For example, the indole ring moiety may be classified in class 548, subclass 503; the quinoline moiety is classified in class 546, subclass 152; the carboxylic acid ester moiety is classified in class 556, subclass 226; the amino moiety is classified in class 564, subclass 305, etc. These distinct species may be included together in a generic claim where the number of species is reasonable and there is a serious burden on the examiner if restriction between these species is required.

A serious burden does exist. The grouping identified supra is distinct from the non-elected grouping that containing the quinoline moiety. The search required, both electronic and manual database, is separate that involves separate search considerations and search strategies. These searches are not co-extensive and the evaluation of the search results are divergent, so much so that a searching for a reference that would anticipate the grouped invention identified

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supra would not even render the non-elected invention obvious. Therefore, a serious burden would be placed on examined if restriction between these groupings were not required.

For these reasons and the reasons of record, the restriction requirement as stated is proper and maintained.

The requirement is still deemed proper and is therefore made FINAL.

III. Objections:

(a) Claims 28, 31, 33, 36, 38, 46, 48, 50 and 53 claim the same compounds as those claims from which they depend and thus are objected to as being substantial duplicates of the claims from which they depend, i.e., claims 27, 30, 32, 35, 37, 45, 47, 49 and 52 respectively.

(b) Claim 1-38, 40-53 and 62 in part are objected to as containing non-elected subject matter. These claims drawn solely to the elected group identified supra and overcoming any objections cited supra would appear allowable. 37 CFR 1.142(b).

(c) Claims 39 and 54-61 and 63 are objected to as being drawn to non-elected inventions. 37 CFR 1.142(b). *Cancelled*

IV. Contacts:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrea D. Small, whose telephone number is (703) 305-0811. The examiner can normally be reached on Monday-Thursday from 8:30 AM - 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

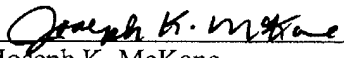
Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [Joseph.McKane@uspto.gov]. All Internet e-mail communications will be made of

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record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1234

Andrea D. Small, Esq.
May 29, 2003



Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626
Technology Center 1